K073105

510(k) Summary
for the
PEEK Spinal Spheres

JAN 3 - 2008

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the PEEK Spinal Spheres.

Date Prepared: October 31, 2007

1. Submitter:
Interbody Innovations LLP
24 Smith Road, Suite 503
Midland, TX 79705

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. Trade name: PEEK Spinal Spheres
Common Name: Spinal device
Classification Name: orthosis, spinal intervertebral fusion, solid sphere
Unclassified
NVR

3. Predicate or legally marketed devices which are substantially equivalent:

The PEEK Spinal Sphere is a modification to the Interbody Innovations Spinal Sphere (K062992) and is substantially equivalent to the and Satellite Spinal System (K060415 – Sofamor Danek, Memphis, TN)

4. Description of the device:

These spheres may be inserted between the vertebral bodies into the disc space from L3 to S1. The Spinal Sphere implants are single use implants and should never be reused under any circumstances. These spheres are available in Ø10-Ø16mm.

Materials:
PEEK Optima per ASTM F2026

Function:
The Spinal Sphere is a spherical implant designed to hold bone parts in alignment while they heal in order to promote interbody fusion.

5. Intended Use:

The Spinal Spheres are intended to be inserted between vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The Spinal Spheres are intended to be used with bone graft.

6. Comparison of the technological characteristics of the device to predicate and legally marketed devices:

This device is substantially equivalent to the Interbody Innovations Spinal Sphere and Satellite Spinal System Satellite Spinal System (K060415). They are the same material, design and indications.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Interbody Innovations, LLP
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Blvd.
Round Rock, TX 78681

JAN - 3 2008

Re: K073105
Trade/Device Name: PEEK Spinal Spheres
Regulation Number: Pre-Amendment
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: NVR
Dated: November 30, 2007
Received: December 7, 2007

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print:

> The safety and effectiveness of this device for use in motion sparing, non-fusion procedures has not been established.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International, and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073105

Device Name: PEEK Spinal Spheres

Indications for Use:

The Spinal Spheres are intended to be inserted between vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The Spinal Spheres are intended to be used with bone graft.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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